DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-015

Braintree Laboratories, Inc
Attention: Vivian A. Caballero
Director of Regulatory Affairs
60 Columbian Street
P.O. Box 850929
Braintree, MA 02185

Dear Ms. Caballero:

Please refer to your new drug application (NDA) dated December 6, 2005, received December 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MiraLAX (polyethylene glycol 3350) powder for solution.

We acknowledge receipt of your submissions dated March 15; May 10; July 19, 21, 26, and 28; August 15 and 16; September 7 and 25; and October 3, 4, 5, and 6, 2006.

This new drug application provides for the over-the-counter use of MiraLAX (polyethylene glycol 3350) powder for solution for the treatment of occasional constipation (irregularity).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1) Revise the shield that appears on the principal display panels for all packages from "Original Rx Strength" to read "Original Prescription Strength."

2) Revise the words "store", "tamper-evident", and "do" in the bulleted statements in the "**Other information**" section to appear in all lowercase letters.

The final printed labeling (FPL) must be identical to, except for including the revisions listed above, the enclosed labeling (immediate container (bottle) label representing the 119 g, 238 g, and 527 g package sizes submitted October 5, 2006, the Drug Facts label text for the 12-count package size outer carton and single dose packet submitted October 5, 2006, the single dose packet principal display panel submitted October 3, 2006, and the carton representing the layout of the outer carton for the 12-count package size submitted October 3, 2006), and must be in the "Drug Facts" format (21 CFR 201.66). The revisions listed above are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product labeling and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies

of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 22-015**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for pediatric patients less than or equal to 16 years of age until October 6, 2016.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of occasional constipation (irregularity) in pediatric patients less than or equal to 16 years of age.

   Final Report Submission: October 6, 2016.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Keith Olin, Regulatory Project Manager, at (301) 301-796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center of Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center of Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
10/6/2006 03:44:14 PM

Andrea Segal
10/6/2006 03:52:20 PM